

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

United States of America,
Plaintiff,

v.

3,985 tablets, more or less,
of an article of drug,
labeled in part:

(bag)

****Suplemento Natural
SHANGAI *** Shangai Regular
Estimulante sexual para
Hombre y Mujer *** 100%
Natural *** Marca Registrada
*** 67390 *** Datos del
Suplemento Tamaño de la
porción: 1 Tableta ****"

2,244 capsules, more or less,
of an article of drug,
labeled in part:

(bag)

**** Para Hombres Super
SHANGAI *** Suplemento
Natural 100% Natural ***
SHANGAI *** Marca Registrada
*** 67390 *** Datos del
Suplemento Tamaño de la
porción: 1 Tableta ****"

171 capsules, more or less,
of an article of drug,
labeled in part:

(bag)

**** SHANGAI *** 100% Natural
Ultra X *** Suplemento
Natural SHANGAI *** Marca
Registrada *** 67390 ***
porción: 1 Tableta ****"

Case No.:08-1241 (SEC)

2,077 capsules, more or less,
of an article of drug,
labeled in part:

(bag)

**** Para Mujeres Lady
SHANGAI *** Suplemento
Natural 100% Natural ***
SHANGAI *** Marca Registrada
*** 67390 *** Datos del
Suplemento Tamaño de la
porción: 1 Tableta ****

and

6,092 capsules, more or less,
of an article of drug,
labeled in part:

(bag)

****Para Hombres Naturalë****
Suplemento Natural 100%
Natural *** Super Plus ***
Datos del Supemento Tamaño de
la porción: 1 Tableta ****",

Defendants.

DEFAULT DECREE OF CONDEMNATION AND DESTRUCTION

On March 25, 2008, the United States of America, through its attorneys, Rosa Emilia Rodriguez Velez, United States Attorney for the District of Puerto Rico, and Jose M. Pizarro-Zayas, Assistant Untied States Attorney, filed in this Court an Amended Verified Complaint for Forfeiture against the above-described articles. The defendant articles are located at the Puerto Rico Department of Health, Drug and Pharmacy

Division, at the former Ruiz Soler Hospital Facilities, Bayamon, Puerto Rico, within the jurisdiction of this Court.

The Amended Complaint alleges that the defendant articles are drugs within the meaning of 21 U.S.C. § 321(g)(1), that may not be introduced or delivered for introduction into interstate commerce, 21 U.S.C. § 355(a), because they are "new drugs" under 21 U.S.C. § 321(p), and no approvals or applications for approval filed pursuant to 21 U.S.C. § 355(b) are in effect for them. The Complaint also alleges that the articles are misbranded while held for sale after shipment in interstate commerce because: (a) their labels fail to reveal that the articles contain the active pharmaceutical ingredients sildenafil, analogs of sildenafil, or tadalafil, which is a material fact with respect to adverse health consequences that may result from use of the articles by individuals with underlying medical conditions and at risk for adverse drug interactions or adverse drug side effects, see 21 U.S.C. §§ 352(a) & 321(n); and (b) their labeling fails to bear adequate directions for use, and they are not exempted from such requirement under 21 CFR § 201.115 because the articles are unapproved new drugs, see 21 U.S.C. § 352(f)(1).

Pursuant to a warrant of arrest in rem issued by this Court, the United States Marshal for this District seized the defendant articles on April 9, 2008.

It appearing that process was duly issued in this action and returned according to law; that public notice of the arrest and seizure of the articles was given according to law; and that no person has appeared to claim the seized articles within the time specified by Supplemental Rule G, it is, on Plaintiff's motion for Default Decree of Condemnation, Forfeiture, and Destruction, hereby

ORDERED, ADJUDGED, AND DECREED, that the default of all persons having any right, title, or interest in the unclaimed seized articles be and is hereby entered; and it is further

ORDERED, ADJUDGED, AND DECREED, pursuant to 21 U.S.C. § 334, that the unclaimed seized articles are drugs within the meaning of 21 U.S.C. § 321(g)(1), that may not be introduced or delivered for introduction into interstate commerce, 21 U.S.C. § 355(a), because they are "new drugs" under 21 U.S.C. § 321(p), and no approvals or applications for approval filed pursuant to 21 U.S.C. § 355(b) are in effect for such drugs; and it is further

ORDERED, ADJUDGED, AND DECREED that the unclaimed seized articles are misbranded while held for sale after shipment in interstate commerce because: (a) their labels fail to reveal that the articles contain the active pharmaceutical ingredients sildenafil, analogs of sildenafil,

or tadalafil, which is a material fact with respect to adverse health consequences that may result from use of the articles by individuals with underlying medical conditions and at risk for adverse drug interactions or adverse drug side effects, see 21 U.S.C. §§ 352(a) & 321(n); and (b) their labeling fails to bear adequate directions for use, and they are not exempted from such requirement under 21 CFR § 201.115 because the articles are unapproved new drugs, see 21 U.S.C. § 352(f)(1); and it is further

ORDERED, ADJUDGED, AND DECREED, pursuant to 21 U.S.C. § 334, that the United States Marshal for this District shall forthwith destroy the unclaimed seized articles and make due return to this Court.

SO ORDERED: The 7TH day of AUG. 2008.




SALVADOR E. CASELLAS
U.S. District Court Judge